

[0018] a) obtaining a sample from the subject/in a sample obtained from the subject

[0019] b) applying a set of nucleic acid primers that specifically hybridize with the nucleotide sequence of at least one gene or full sequence or target sequence selected from Table 1 to the sample from the subject

[0020] c) specifically amplifying the nucleotide sequence using the set of nucleic acid primers

[0021] d) detecting the amplification products using a specific detection agent to determine the level of the at least one gene or full sequence or target sequence

[0022] e) wherein the determined level of the at least one gene (or full sequence or target sequence) is used to provide a characterisation of and/or a prognosis for the cancer, such as prostate cancer or ER positive breast cancer. Suitable primers and primer pairs are listed in Table 1B.

[0023] The detection agent may comprise a label, such as a fluorescence label or fluorophore/quencher system attached to the nucleic acid probe and/or primer (as appropriate). Suitable systems and methodologies are known in the art and described herein.

[0024] The characterization, prognosis or diagnosis of the cancer, such as prostate cancer or ER positive breast cancer can also be used to guide treatment.

[0025] Accordingly, in a further aspect, the present invention relates to a method for selecting a treatment for a cancer, such as prostate cancer or ER positive breast cancer in a subject comprising:

[0026] (a) determining the expression level of at least one gene selected from Table 1 in a sample from the subject wherein the determined expression level is used to provide a characterisation of and/or a prognosis for the cancer, such as prostate cancer or ER positive breast cancer and

[0027] (b) selecting a treatment appropriate to the characterisation of and/or prognosis for the cancer, such as prostate cancer or ER positive breast cancer.

[0028] In yet a further aspect, the present invention relates to a method for selecting a treatment for a cancer, such as prostate cancer or ER positive breast cancer in a subject comprising:

[0029] (a) determining the expression level of at least one gene selected from Table 1 in a sample from the subject wherein the determined expression level is used to provide a characterisation of and/or a prognosis for the cancer, such as prostate cancer or ER positive breast cancer

[0030] (b) selecting a treatment appropriate to the characterisation of and/or prognosis for the cancer, such as prostate cancer or ER positive breast cancer and

[0031] (c) treating the subject with the selected treatment.

[0032] The invention also relates to a method of treating cancer, such as prostate cancer or ER positive breast cancer comprising administering a chemotherapeutic agent or radiotherapy, optionally extended radiotherapy, preferably extended-field radiotherapy, to a subject or carrying out surgery on a subject wherein the subject is selected for treatment on the basis of a method as described herein.

[0033] In a further aspect, the present invention relates to a chemotherapeutic agent for use in treating a cancer, such as prostate cancer or ER positive breast cancer in a subject, wherein the subject is selected for treatment on the basis of a method as described herein.

[0034] In yet a further aspect, the present invention relates to method of treating a cancer, such as prostate cancer or ER positive breast cancer comprising administering a chemo-

therapeutic agent or radiotherapy, optionally extended radiotherapy, preferably extended-field radiotherapy to a subject or carrying out surgery on a subject wherein the subject has an increased expression level of at least one gene with a positive weight selected from Table 1 and/or wherein the subject has a decreased expression level of at least one gene with negative weight selected from Table 1.

[0035] The invention also relates to a chemotherapeutic agent for use in treating a cancer, such as prostate cancer or ER positive breast cancer in a subject, wherein the subject has an increased expression level of at least one gene with a positive weight selected from Table 1 and/or wherein the subject has a decreased expression level of at least one gene with a negative weight selected from Table 1.

[0036] In certain embodiments according to all relevant aspects of the invention the chemotherapeutic agent comprises, consists essentially of or consists of

[0037] a) an anti-hormone treatment, preferably bicalutamide and/or abiraterone

[0038] b) a cytotoxic agent

[0039] c) a biologic, preferably an antibody and/or a vaccine, more preferably Sipuleucel-T and/or

[0040] d) a targeted therapeutic agent

[0041] Suitable therapies and therapeutic agents are discussed in further detail herein. The treatment may comprise or be adjuvant therapy in some embodiments.

[0042] According to all aspects of the invention the cancer may be a prostate cancer or ER positive breast cancer. Typically, the cancer is a primary tumor. In some embodiments, the prostate cancer may be a primary prostate cancer.

[0043] It is shown herein that the gene signatures may have particularly advantageous utility when combined with determination of other prognostic factors. Thus, all aspects of the invention may include other prognostic factors in the characterization, diagnosis or prognosis of the cancer. This may comprise generation of a combined risk score. This is particularly applicable in the context of prostate cancer. Other prognostic factors include prostate specific antigen (PSA) levels and/or Gleason score. MRI scan results may also be taken into account. Thus, according to all aspects of the invention, characterization, prognosis or diagnosis may take into account other prognostic factors such as PSA levels and/or Gleason score. PSA is a well-known serum biomarker and may be used according to the invention, in particular when measured pre-operatively. For example, a PSA value of 4-10 ng/ml may be considered "low risk". A PSA value of 10-20 ng/ml may be considered reflective of "medium risk". A PSA value of 20 ng/ml or more may be considered reflective of "high risk". High risk would correspond to poor prognosis and/or be indicative of aggressive disease. Levels of PSA may contribute towards a final characterization of the cancer in combination with the measured expression levels. Medium risk PSA levels when combined with a positive or high signature score may indicate poor prognosis.

[0044] The Gleason system is used to grade prostate tumours with a score from 2 to 10, where a Gleason score of 10 indicates the most abnormalities. Cancers with a higher Gleason score are more aggressive and have a worse prognosis. The system is based on how the prostate cancer tissue appears under a microscope and indicates how likely it is that a tumour will spread. A low Gleason score means the cancer tissue is similar to normal prostate tissue and the tumour is less likely to spread; a high Gleason score means